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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/605,213	06/28/2000	Norbert Rahn	P00,1268	6581

7590

01/29/2004

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EXAMINER

MANTIS MERCADER, ELENI M

ART UNIT	PAPER NUMBER
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3737

17

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/605,213

Applicant(s)

RAHN ET AL.

Examiner

Eleni Mantis Mercader

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-10, 15-17 and 31-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-10, 15-17 and 31-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 15, 3-10 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paltieli'029 in view of Yanof et al.'904.

Paltieli'029 teaches all the features of the instant invention including: a system, a medical workstation, and a method comprising:

an image acquisition unit for acquiring image signals of a first subject an imaging unit for producing an image of the first subject from the image signals (see Figure 1, element 28, col. 6, lines 20-28);

a navigation system including a position acquisition system for determining a position of said image signal acquisition unit (see Figure 1, element 20; and col. 6, lines 29-40) and for determining a position of a second subject relative to said image acquisition unit (see Figure 1, element 32; and col. 6, lines 40-57);

a mixing unit for mixing a representation of said second subject into said image of said first subject (col. 7, lines 42-67 and col. 8, lines 1-63; also see Figures 7-10).

Paltieli'029 teaches a navigation system including identifiers, selected from the group consisting of detectable marks and position sensors, which are respectively attachable to said

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image signal acquisition unit and to said second subject and which are identifiable as to position by said position acquisition unit (see Figures 1 and 4; in Figure 4, elements 60 and 62; also see col. 6, lines 66-67 and col. 7, lines 1-18).

Paltieli'029 teaches the image signal acquisition unit which comprises an ultrasound probe (Figure 1, element 28; col. 6, lines 23-27).

Paltieli'029 teaches the image signal acquisition unit comprising an X-ray source and an X-ray receiver (see Figure 2, elements 42 and 40; and col. 6, lines 58-65).

Paltieli'029 teaches the imaging unit producing a 3D image of said first subject from said image signals (col. 8, lines 32-63).

Paltieli'029 teaches the imaging unit producing a 2D image of said first subject from said image signals (col. 8, lines 20-31) and wherein the mixing unit mixes an indication of a distance of the second subject from the image plane into the 2D image (see Figures 7-10; in Figure 8 see screen 106, indicating needle 92 on ultrasound image 108; also see col. 8, lines 11-32).

Paltieli'029 teaches the position acquisition unit simultaneously identifies the position of said image signal acquisition unit and the position of the second subject and indicating a projection of the tip into the 2D image as indicated by the dotted line (see Figures 4 and 7; and col. 6, lines 66-67 and col. 7, lines 1-67).

Paltieli'029 teaches an acceptance device for the first subject and wherein the position acquisition device identifies a position of the acceptance device simultaneously with identifying the position of the image signal acquisition unit and the position of the second subject (the verification computer unit constitutes such a device for verifying needle insertion based on positions of the subject based on the ultrasound image and the target; see col. 9, lines 46-63).

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Paltieli'029 does not teach a mixing unit connected to the imaging unit for mixing a representation of said tip into said 2D image and if the said tip is not located in said image plane, for mixing a designation of the distance of the tip from the image plane into the 2D image said designation being alterable and indicating a magnitude of said distance.

In the same field of endeavor, Yanof et al.'904 teach in stereotactic systems utilization of a mixing unit for creating a composite image of the location of the tip as well as the tube of an instrument (see Figure 4 and abstract). They further teach that if the tip is not located in the image plane but a distance away, mixing a designation of the distance of the tip from the image plane into the 2D image, notice the trajectories and the indicia demonstrating the distance from each of the slices composing the volumetric image (see Figure 4 and see col. 7, lines 33-65).

It would have been obvious to one skilled in the art at the time that the invention was made to have modified Paltieli'029 and incorporated the teaching of Yanof et al.'904 to allow for better position monitoring of the instrument while in surgery in different imaging planes to improve interventional guidance (see for motivation to combine ^{in Yanof et al.'904} col. 1, lines 64-67 and col. 2, lines 1-15).

3. Claims 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paltieli'029 in view of Yanof et al.'904 as applied to claim 15 above, and further in view of Manwaring et al.'819.

Regarding claim 32, Paltieli'029 in view of Yanof et al.'904 teach all the features of the instant invention except for the teaching of using a circle having a diameter, which is alterable according to the magnitude of the distance. Manwaring et al.'819 teach using a circle having a diameter, which is alterable according to the magnitude of the distance (col. 10, lines 23-25;

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referring to distance-to-target feature circle 126 changing according to the distance of the probe tip from the target). It would have been obvious to one skilled in the art at the time that the invention was made to have modified Paltieli'029 in view of Yanof et al.'904 and incorporated the teaching of Manwaring et al.'819 to incorporate the distance-to-target feature circle 126 and superimpose this feature to all of the planes of interest to further assist the operator in determining how far the tip of the probe is from the target of interest as related to all of the planes of interest.

Regarding claim 33, Paltieli'029 in view of Yanof et al.'904 teach all the features of the instant invention except for the teaching of using color to guide the instrument. Manwaring et al.'819 teach using different colors in the 4 quadrants to further guide targeting the instrument (col. 8, lines 25-44). It would have been obvious to one skilled in the art at the time that the invention was made to have modified Paltieli'029 in view of Yanof et al.'904 and incorporated the teaching of Manwaring et al.'819 in order to easily determine the location of the instrument and its distance to target by using the different colors to further assist in localizing the instrument.

4. Claims 16-17 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cosman'072 in view of Graumann'180 .

Cosman'072 teaches an optical tracking system to track a variety of diagnostic imaging modalities including a 3D imager utilizing x-rays and coordinating the treatment device (LINAC constituting the surgical instrument), the patient and the couch/bed/or support as indicated in Figures 1, 7 and 11 (see col. 8, lines 43-55 and col. 14, lines 20-42 and see x-ray 3D volumetric imager as depicted in Figure 11) and a mixing unit for mixing a representation of the second unit

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or the surgical instrument into the 3D image as it relates to the acquisition system (see monitor of Figure 2 and see Figure 7 and 11).

Cosman'072 does not teach a C-arm X-ray image signal acquisition unit for producing a 3D image of a first subject and a position acquisition system for determining the position of the C-arm X-ray acquisition imager.

In the same field of endeavor, Graumann'180 teach a C-arm X-ray image signal acquisition unit for producing a 3D image of a first subject and a position acquisition system for determining the position of the C-arm X-ray acquisition imager (see the Figure and see col. 4, lines 18-67; col. 5, lines 1-67; col. 6, lines 1-67 and col. 7, lines 1-6).

It would have been obvious to one skilled in the art at the time that the invention was made to have modified Cosman'072 and incorporated the teaching of Graumann'180 to utilize a trackable C-arm x-ray imager as opposed to a CT imager as an alternative functional equivalent of creating a 3D volumetric image utilizing x-rays.

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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eleni Mantis Mercader whose telephone number is 703 308-0899. The examiner can normally be reached on Mon. - Fri., 8:00 a.m.-6:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dennis Ruhl can be reached on 703 308-2262. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0858.


Eleni Mantis Mercader
Primary Examiner
Art Unit 3737

EMM